REMARKS

A restriction requirement under 35 U.S.C. §§121 and 372 was set forth in the Official Action dated December 18, 2006 in the above-identified patent application.

At the outset, it is noted that a shortened statutory response period of one (1) month was set forth in the December 18, 2006 Official Action. Therefore, the initial due date for response is January 18, 2007. This response is being filed within the initial one (1) month response period.

It is the Examiner's position that claims 1-18 in the present application are drawn to six (6) patentably distinct inventions which are as follows:

Group I:	Claims 1-6, drawn to a cell-line that replicates hepatitis C virus (HCV), classified in class 435, subclass 325.
Group II:	Claims 7 and 8, drawn to a host animal comprising cells that replicate HCV, classified in class 800, subclass 9.
Group III:	Claims 9-12, drawn to a method for producing cell-lines capable of producing HCV, classified in class 435, subclass 325.
Group IV:	Claim 13 and 16-18, drawn to a method for screening test compounds which inhibit HCV replication or modulate the antiviral response of interferon alpha, classified in class 435, subclass 325.
Group V:	Claim 14, drawn to an HCV polynucleotide, classified in class 514, subclass 44.
Group VI:	Claim 15, drawn to an HCV polyprotein, classified in class 514, subclass 2.

The Examiner asserts that Groups I - VI do not relate to a single inventive concept under PCT Rule 13.1. It is

the Examiner's position that the common technological feature (i.e., the ability of cell lines to support replication of HCV) was allegedly disclosed by Germi et al. (J. Med. Virol. (2001) 64:6-12).

Applicants respectfully disagree with the Examiner's position and submit that a withdrawal of the instant restriction requirement is clearly in order for the following reasons.

First, Applicants respectfully submit that during the international stage of this application, the PCT Examiner did not make a lack of unity finding and considered all of the claims to be directed to a single invention. Plainly, the instant restriction requirement fails to comply with the established United States Patent and Trademark Office practice of following the international rules regarding unity of invention in the prosecution of applications filed under §371. While the Examiner purports to employ the general inventive concept practice under PCT Rule 13.1, it is wholly unclear how the Examiner could conclude that the instant application has six (6) Groups of inventions, when the PCT Examiner, employing the same rules, determined that the claims in the international application have complete unity of invention. Accordingly, Applicants respectfully request the instant restriction requirement be withdrawn and all of the claims be examined on their merits.

Second, Applicants respectfully submit that the restriction requirement set forth above is improper for failure to comply with the relevant provisions of the Manual of Patent Examining Procedure (MPEP) pertaining to unity of invention determinations. As stated in §1893.03(d) of the MPEP:

> Examiners are reminded that unity of invention (not restriction) practice is applicable in international applications (both Chapter I and II) and in national stage applications submitted under 35 U.S.C. 371.
>
> The principles of unity of invention are used to determine the types of claimed subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application.
>
> The basic principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept.
>
> A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features refers to those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art.

The Examiner further contends that the common technical feature of the claimed inventions is not novel and is anticipated by Germi et al., who teach that mosquito (biological order: diptera) and African green monkey (biological order: primate) derived cell-lines are capable of replicating HCV. In the interest of expediting prosecution of the instant application, claims 1 and 4 have been amended to recite that the cell line is a non-monkey, non-chimpanzee, non-mosquito cell line and a human non-hepatic cell line in light of this prior art reference. The present amendments to claims 1 and 4 cannot be regarded

as new matter when considered in light of In re Johnson, which stands for the proposition that an applicant for patent may narrow his or her claims to avoid having them read on subject matter which an applicant is not entitled to claim. 558 F.2d 1008 (CCPA 1977). Claim 1 now sets out and circumscribes a particular area with a reasonable degree of precision and particularity, In re Angstadt, 537 F.2d 498 (CCPA 1976), (i.e., any cell which replicates HCV with the exclusion of monkey and mosquito cells). Applicants are permitted to determine what bounds of protection to seek. In regard to currently amended claim 1, "[the current] specification, having described the whole, necessarily described the part remaining." See MPEP §2173.05(i); quoting In re Johnson, 558 F.2d at 1019.

Applicants also respectfully submit that Groups I and Group III are clearly related as product and process of making (See MPEP §806.05(f)) and respectfully request that Group III be included with Group I. Notably, claims 1-6 of Group I are drawn to a cell-line that replicates HCV produced by the methods as described in claims 9-12 of Group III. The current amendments to claim 11 find support at page 27, lines 13-14 of the specification. New claim 19 finds support in the original claims and at page 27, lines 10-20. Clearly, a search of cell-lines that replicate HCV will necessarily include methods for producing cell-lines capable of producing HCV and will not present a "serious search burden" on the Examiner, as is required under MPEP §803. Moreover, in accordance with §821.04 of the MPEP, "if applicant elects claims directed to the product, and the product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim

will be rejoined." Therefore, Applicants respectfully request the withdrawal of the restriction requirement, or at the very least, the rejoinder of Group III with Group I upon the allowance of a product claim to the cell-lines.

For all of the foregoing reasons, Applicants respectfully request withdrawal, or at the very least, modification of the present restriction requirement.

In order to be fully responsive to the instant restriction requirement, Applicants hereby elect, with traverse, Group I, namely claims 1-6 drawn to a cell-line that replicates hepatitis C virus (HCV), classified in class 435, subclass 325. Applicants reiterate their desire to seek rejoinder of the method claims which will include all the features of the product claims, should the product claims be found in condition for allowance.

Applicant's elections in response to the present restriction requirement are without prejudice to their right to file one or more continuing applications, as provided in 35 U.S.C. §120, on the subject matter of any claims finally held withdrawn from consideration in this application.

Early and favorable action on the merits of this application is respectfully solicited.

Respectfully submitted,
DANN, DORFMAN, HERRELL AND SKILLMAN
A Professional Corporation

By _____
Kathleen D. Rigaut, Ph.D., J.D.
PTO Registration No. 43,047

Telephone: (215) 563-4100
Facsimile: (215) 563-4044
Email: krigaut@ddhs.com